REMARKS

In view of the above amendments and the following remarks, reconsideration of the objections and rejections contained in the Office Action of February 26, 2009 is respectfully requested.

In order to make necessary editorial corrections, the entire specification and abstract have been reviewed and revised. As the revisions are quite extensive, the amendments to the specification and abstract have been incorporated into the attached substitute specification and abstract. For the Examiner's benefit, a marked-up copy of the specification indicating the changes made thereto is also enclosed. No new matter has been added by the revisions. Entry of the substitute specification is thus respectfully requested.

The Examiner objected to claim 16 due to an informality. However, claim 16 and all of the remaining previously-pending claims have now been cancelled and replaced with new claims 25-44. All of the new claims have been drafted in order to address the Examiner's objection, and so as to place the previously-pending claims in a preferred form. Consequently, it is submitted that the Examiner's objection to the previously-pending claims has been overcome.

The Examiner rejected all of the previously-pending claims in view of the prior art. In particular, the Examiner rejected previously-pending independent claim 11 as being anticipated by the Berg '048 reference (USP 6,451,048) or as being anticipated by the Berg '377 reference (U.S. Publication 2003/0018377). In addition, the Examiner rejected all of the previously-pending dependent claims as being anticipated by the Berg '048 reference or by the Berg '377 reference, or as being unpatentable over the Berg '048 reference in view of the Perez reference (USP 6,984,244), as being unpatentable over the Berg '377 reference in view of the Berg '048 reference; as being unpatentable over the Berg '377 reference in view of the Bender reference (USP 7,267,682); or as being unpatentable over the Berg '377 reference in view of the Berg '048 and the Perez reference. However, as noted above, all of the original claims have been cancelled and replaced with new claims 25-44. For the reasons discussed below, it is respectfully submitted that the new claims are clearly patentable over the prior art of record.

It has been known to place a tubular prosthesis inside a blood vessel so as to enlarge or strengthen the blood vessel. However, it has been difficult to ensure that conventional prostheses are maintained in their proper position within the blood vessel (i.e., ensure that the prostheses are not moved along the blood vessel due to the force of the blood flow). Conventional fasteners for attaching the prosthesis to the blood vessel to maintain the position of the prosthesis have been unacceptable, primarily because the fasteners are separate from the prosthesis and are inserted after the prosthesis is inserted so as to make the fastening process very difficult and unreliable (see page 1 of the original specification). The present invention addresses this problem.

A brief discussion of the features and advantages of the present invention as recited in the new claims will now be provided below with reference to various portions of the present application. However, reference to any drawings or portions of the specification is provided only for illustrative purposes, and is not intended to otherwise limit the scope of the claims to any particular embodiments.

New independent claim 25 is directed to a radially deformable endovascular prosthesis, as illustrated in Figure 1. In particular, the prosthesis comprises a lattice 12 deformable between a retracted state with a small diameter (see Figure 3A) and an expanded state with a large diameter (see Figure 4A), and at least two external hooks 18 configured to define a clamp 16 for anchoring the prosthesis to external tissue (see Figure 5A). The lattice 12 includes crossed wires arranged to define meshes. The at least two hooks 18 are connected to the wires of the lattice 12 *at opposite sides of one of the meshes of the lattice 12* such that the one of the meshes has a first shape when the lattice is in the retracted state so that the at least two hooks 18 of the clamp 16 are in a spaced-apart position (see Figure 3A), and such that the one of the meshes has a second shape when the lattice is in the expanded state so that the at least two hooks 18 of the claim 16 are in a close-together position (see Figure 5A; and page 6, lines 5-9 of the original specification).

As now clearly recited in new independent claim 25, there is a structural relationship between the meshes of the lattice and the location at which the hooks 18 are attached to *opposite sides* of one of the meshes. As a result, by simply allowing the lattice to deform into the

expanded state with the large diameter, the at least two hooks will move to the close-together position to define the clamp engaging the tissue so as to anchor the prosthesis to the blood vessel (see page 8, lines 13-19 of the original specification).

The Berg '377 reference teaches a body which can be inserted into a biological passage. A balloon is inflated so as to expand the body toward the inner surface of the passage, and the body can include anchors to be inserted into the passage wall due to expansion of the body. In particular, Figure 33 of the Berg '377 reference illustrates a band 3302 which includes several outwardly-extending anchors 3310 having sharp points 3340. As the balloon 3390 expands the band 3302, the anchors 3310 are inserted into the passage walls 2028, as illustrated in Figure 34. However, the Berg '377 reference does not teach or suggest a lattice including crossed wires arranged to define meshes. Moreover, the Berg '377 reference does not teach a prosthesis in which at least two hooks are connected to the wires of the lattice *at opposite sides of one of the meshes of the lattice* such that, in a retracted state of the lattice, the at least two hooks are in a spaced-apart position, and such that, in an expanded state of the lattice, the at least two hooks are in a close-together position. Therefore, the Berg '377 reference clearly does not anticipate or even render obvious new independent claim 25.

The Berg '048 reference is directed to a wire connector structure for tubular graphs. As illustrated in Figure 5, the connector structure includes hooks 52 connected to a wire lattice 48 by connectors 34. As clearly illustrated in Figure 5 and discussed in column 5, lines 23-25, the connectors 34 are connected to the lattice 48 at attachment points 50, and the attachment points span 3 or 4 meshes of the lattice 48, and are all located on *the same side* of each mesh. In other words, the Berg '048 reference does not teach at least two hooks connected to the wires of a lattice *at opposite sides of one of the meshes of the lattice*. Moreover, the Berg '048 reference does not teach the connection of at least two hooks to the lattice such that the meshes have a first shape when the lattice is in a retracted state of the lattice so that the hooks of the clamp are in a spaced-apart position, and such that the meshes have a second shape when the lattice is in an expanded state so that the hooks are in a close-together position.

On page 3 of the outstanding Office Action, the Examiner stated that the device of the Berg '048 reference "is being considered a radially deformable endovascular prosthesis because it is *capable of* being radially deformed and *capable of* being deployed within the vasculature" (empahsis added) However, new independent claim 25 now clearly recites with more particularity the structural relationship between the hooks and the lattice. Specifically, rather than simply reciting that the prosthesis is radially deformable, claim 25 now clearly recites that the hooks are connected to the wires of the lattice at opposite sides of the mesh in a particular manner such that, when the lattice is in the retracted state, the hooks are in a spaced-apart position. Alternatively, when the lattice is in the expanded state, the hooks are in the close-together position. Therefore, as explained above, simple expansion of the lattice from the retracted state to the expanded state will move the hooks together so as to form a clamp and attach the prosthesis to the wall of a blood vessel. The Berg '048 reference does not teach or even suggest these features now clearly recited in independent claim 25, and there is not even a suggestion that the structure of the Berg '048 reference is even capable of functioning in this manner due the specific nature of the structure required to function in this manner. Consequently, the Berg '048 reference does not anticipate or even render obvious new independent claim 25.

The Examiner applied the Perez reference as teaching a "holding means," and applied the Bender reference as teaching a staple having ends in the form of a shepherd's hook. However, the Perez reference and the Bender reference do not teach or suggest the arrangement of a lattice and at least two hooks as now recited in independent claim 25. Accordingly, the Perez reference and the Bender reference do not correct the deficiencies in the Berg '048 reference or the Berg '377 reference as discussed above. Accordingly, it is respectfully submitted that new independent claim 25 and the claims that dependent therefrom are clearly patentable over the prior art of record.

New independent claim 36 is directed to a kit for treating a blood vessel, comprising a radially deformable endovascular prosthesis including all of the limitations of new independent

claim 25. Accordingly, for the reasons discussed above with respect to new independent claim 25, it is submitted that new independent claim 36 is also clearly patentable over the prior art of record.

In view of the above amendments and remarks, it is submitted that the present application is now in condition for allowance. However, if the Examiner should have any comments or suggestions to help speed the prosecution of this application, the Examiner is requested to contact the Applicant's undersigned representative.

Respectfully submitted,

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Version with Markings to Show Changes Made

A TUBULAR PROSTHESIS

BACKGROUND OF THE INVENTION

The present invention relates to a tubular prosthesis of the type that is radially deformable, comprising a lattice that is deformable between a retracted state of small diameter and an expanded state of larger diameter.

For various types of treatment, it is known to place a tubular prosthesis inside a blood vessel, whether a vein or an artery. Such tubular prostheses are generally referred to by the term "stent".

The prosthesis is brought to the inside of the vessel while it is in its retracted state, and then for positioning purposes, the prosthesis is expanded so as to press against the inside surface of the vessel. This expansion is performed either automatically because of the elasticity of the prosthesis lattice, or else under drive from an internal balloon being inflated, leading to plastic deformation of the material constituting the lattice.

It is difficult to ensure that the prosthesis is held axially within the vessel, i.e. in the long direction of the vessel, and the prosthesis runs the risk of being moved along the vessel under drive from the flow of blood. In addition, the prosthesis runs the risk of not being pressed exactly against the surface of the blood vessel, because of its irregular section.

In order to avoid such movement, it is known that the end of the metal lattice can ~~present~~have outwardly-projecting catches suitable for penetrating into the wall of the vessel so as to prevent the prosthesis from moving axially.

It is also known to secure the prosthesis to the wall of the vessel, e.g. by putting clips into place, which clips are fitted after the prosthesis has been put into place.

Those fastener means are not very reliable and they are difficult to put into place.

SUMMARY OF THE INVENTION

An object of the invention is to provide a tubular prosthesis which can be positioned reliably and which is relatively easy to put into place.

To this end, the invention provides a tubular prosthesis of the above-specified type~~, characterized in that it~~. The prosthesis includes at least two external hooks defining between them a clamp for hooking in external tissue, the two hooks being carried by the lattice and being movable between a spaced-apart position in which the clamp is open, and a closer-together position in which the clamp is closed.

In particular embodiments, the tubular prosthesis includes one or more of the following characteristics:

· each hook is connected to the lattice from a connection end, and the hooks of a given clamp are movable relative to each other during deformation of the prosthesis;

· the lattice comprises crossing wires that form meshes in the form of deformable quadrilaterals, and each hook is connected to the lattice in a corner of a quadrilateral;

· each hook is welded or soldered to the lattice at its connection end;

· each hook is extended at its connection end by a strand that is twisted around the lattice;

· each hook of a given clamp presents the shape of a shepherd's crook at its hooking end, the two hooks overlapping at least in part in order to form ~~said~~the clamp;

· each hook is in the form of a substantially rectilinear blade, the two hooks extending facing each other and spaced apart from each other when the clamp is open; and

· the lattice is elastically deformable towards its expanded position.

The invention also provides a kit for treating a blood vessel, the kit being characterized in that it comprises:

· a prosthesis as defined above;

· means for holding the lattice in the retracted state in the region of ~~the or~~ each clamp; and

· a lattice-delivery tube defining a confinement duct for confining the prosthesis in its retracted state.

In a particular embodiment, the confinement duct of the delivery tube includes longitudinal channels for receiving the hooks.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention can be better understood ~~on~~upon reading the following description given purely by way of example and made with reference to the drawings, in which:

· Figure 1 is a perspective view of a tubular prosthesis in the expanded state;

· Figure 2 is a section view on a larger scale showing the prosthesis in the expanded state in a region that includes a clamp;

· Figure 3A is a cross-section view of the prosthesis in the retracted state;

· Figure 3B is a perspective view of the prosthesis being implanted while in the retracted state of Figure 3;

· Figure 3C is a section view on a larger scale showing the prosthesis in the retracted state in a region that includes a clamp in the open position;

· Figure 4A is a view identical to that of Figure 3A showing the prosthesis expanded prior to hooking;

· Figure 4B is a perspective view of the expanded prosthesis prior to hooking;

· Figure 5A is a view identical to Figure 3A showing the prosthesis expanded and hooked after the clamp-retaining members have been withdrawn;

· Figure 5B is a perspective view of the expanded prosthesis after the clamp-retaining members have been withdrawn; and

· Figures 6 and 7 are perspective and elevation views of various embodiments of the prosthesis of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The tubular prosthesis 10 shown in Figure 1 is ~~for putting~~to be put into place in a blood vessel. It comprises a tubular lattice 12 that is embedded in a film 14 over substantially the entire length of the prosthesis. In the vicinity of one of its ends, the prosthesis also comprises three clamps 16 that are angularly spaced apart regularly at (evenly around) its periphery.

Each clamp 16 is made up of two hooks 18 carried by the metal lattice 12. These hooks can be moved relative to each other between a spaced-apart position in which the clamp is open, and a close-together position in which the clamp is closed.

The clamps 16 are provided on an end segment 20 of the prosthesis that does not have any film 14, the lattice 12 thus not being covered in this region. In contrast, the main ~~region~~segment of the prosthesis, ~~referenced~~indicated by reference number 22, has the lattice 12 embedded in the film 14.

The lattice 12 is made of stainless steel of biocompatible quality. For example, it is made by braiding or knitting a wire, axially expanding a tube, or by any other suitable technique.

In the embodiment shown in Figure 1, the lattice 12 is constituted by two bundles of wires wound helically in opposite directions, the wires in any one bundle

generally extending parallel to one another and across the wires of the bundle of wires that are wound in the opposite direction to form meshes.

The wires in the two oppositely-wound bundles cross over and under one another in alternation.

The lattice 12 is preferably elastically deformable to expand radially between a small diameter retracted state and a larger diameter expanded state.

In its expanded state, shown in Figure 1, the meshes of the lattice form lozenges that are generally ~~elongate~~elongated in the circumferential direction (i.e., circumferentially-elongated lozenge-shaped meshes). In contrast, and as shown in Figure 3B, when the prosthesis is in the retracted state, the meshes form lozenges that are ~~elongate~~elongated parallel to the axis of the prosthesis (i.e., axially elongated logenge-shaped meshes).

In a variant, the prosthesis is plastically deformable, i.e. the lattice presents a first stable shape of small diameter and a second stable shape of larger diameter.

Over its main segment 22, the lattice 12 is completely embedded in the film 14. This film is constituted by a material that is stretchable and liquid-proof, and it fills the meshes.

This material is sufficiently stretchable to enable the film 14 to follow the deformation of the lattice from its retracted state to its expanded state without tearing or becoming unstuck, and in spite of the meshes of the lattice deforming. Suitable materials are biocompatible elastomers such as a natural or synthetic rubber or indeed a biocompatible polymer such as a polyurethane.

The lattice 12 can be coated with the film 14 by a co-extrusion technique or a dipping technique, after the metal has been degreased and treated with a bonding primer.

As shown in Figure 2, each of the hooks 18 forms a metal wire segment having a free end that is curved outwards to form the shape of a shepherd's crook 24. The crook 24 extends a rectilinear segment 26. The hooks 18 overlap at least in part in order to form a clamp 16.

At its end opposite from the crook 24, each segment 26 is bonded to the metal lattice 12 in the opposite corners of a mesh by weld or solder tacking 28, visible in Figure 1. The crooks 24 project outwards from the tubular segment defined by the lattice 12, and, at rest, the curved ends of the crooks lie in a plane extending transversely to the tubular prosthesis, i.e. perpendicular to its general (central) axis, as can be seen in Figure 2.

The diameter of the crooks 24 forming the hooks lies in the range 0.5 millimeters (mm) to 4 mm, whereas the length of the arms 26 lies in the range 3 mm to 12 mm. The crooks 24 forming the curved ends of the hooks preferably have a diameter lying in the range one-fourth to one-eighth the length of the arm 26 of the hook.

The length of the arms 26 is such that when the prosthesis is in the expanded state as shown in Figure 1, the two crooks of the hooks 18 are moved towards each other and together define a loop that is closed or practically closed.

Initially, and as shown in Figures 3A, 3B, and 3C, the prosthesis is associated with means (retaining device) 30 for retaining the clamps 16 in the open position.

In addition, the prosthesis having its clamps held open is received in a conventional manner in a delivery tube 32, within which the prosthesis is confined in its retracted state.

Advantageously, the inside duct of the tube 32 ~~presents~~ has longitudinal channels 33 for receiving the ends of the hooks 18 that project from the generally tubular surface of the metal lattice.

As shown in Figures 3B and 3C, each means for holding a clamp open comprises a flexible tube 34, e.g. made of polyether ether ketone (PEEK). The tube 34 extends longitudinally between a distal end 36 for being received in the blood vessel, and a proximal end 38 designed to be accessible to the surgeon outside the body of the patient. Thus, the tube 34 may be about 1 meter (m) long.

A retaining opening 40 is provided in the side of the tube 34 generally in register with (corresponding to) the associated clamp 16. The tube 34 is also fitted, in the vicinity of its proximal end 38, with a hollow side branch 42 fitted with a ring 43 for axially locking a sliding thread.

The releasable retaining ~~means~~ device 30 also ~~comprise~~comprises a retaining rod 44 engaged axially in ~~the~~ each tube 34, and a retaining thread 46 going round the mesh of the prosthesis that carries the clamp 16.

The retaining rod 44 extends from one end of the tube 34 to the other. It projects out from the tube at the proximal end 38.

This rod is movable inside the tube 34 between a retaining position, in which the rod faces the opening 40, and a release position, in which the rod 44 is spaced apart from the opening 40 and is offset towards the proximal end of the tube 34.

The retaining thread 46 comprises a single strand having an eyelet 48, a tightening loop 50, and a control segment 52 that extends along the entire length of the tube 34 from the opening 40 to the branch connection 42 from which it projects after passing through a locking ring 43.

The end eyelet 48 is constituted by a closed loop of small diameter through which the rod 44 is initially engaged when it is in its retaining position. The ~~lightening~~tightening loop 50 is formed by a strand

segment engaged slidably through two meshes of the lattice adjacent to the mesh carrying the clamp 16.

The ~~lightening~~tightening loop passes through the opening 40 to join the eyelet 48 at one end and the control segment 52 at its other end. The active length of the tightening loop 50 is variable as a function of the traction exerted on the control segment 52, so that it controls the shape of the mesh carrying the clamp 16, as explained below.

Initially, prior to being put into place, the prosthesis is placed in the delivery tube 32, and the control segments 52 of the clamp-retaining ~~means~~device 30 are under tension such that the clamps are held open, as shown in Figure 3B. In this position, the tightening loop 50 tightens the mesh carrying the clamp so that the ~~lozenge defining the~~lozenge-shaped mesh is ~~elongate~~elongated along its diagonal that is parallel to the axis of the prosthesis.

To put the prosthesis into place, it is inserted together with the tube 32 into the delivery zone, and then the tube 32 is withdrawn, thereby releasing the prosthesis. The prosthesis expands and then becomes pressed against the inside surface of the blood vessel, as shown in Figures 4A and 4B.

During this expansion, the meshes of the prosthesis lattice extend because of the elasticity of the lattice so that the peripheral diagonal of the prosthesis lengthens, thus enabling the diameter of the prosthesis to be increased. In contrast, the meshes carrying clamps remain contracted, as shown in Figure 4B, because of the tightening loops 50. Thus, the clamps 16 are docked against the surface of the blood vessel while they are still in the open position.

By acting on the locking ring 43, the practitioner then proceeds to release the retaining thread 46 so as to allow the meshes carrying the clamps to deform elastically, thereby causing pairs of opposite hooks to

move towards each other, closing each clamp, and causing the hooks to penetrate into the wall defining the blood vessel, as shown in Figures 5A and 5B.

After the retaining threads 46 have been released, the rod 44 is brought into the release position, such that the eyelet 48 is released from the rod 44. The practitioner then pulls on the control segment 52, enabling the retaining thread to escape from the metal lattice, traveling through the two meshes adjacent to the mesh carrying the clamp.

Thus, since the clamp-retaining ~~means~~device have been made independent of the prosthesis, they can be extracted along an endoluminal path.

It will be understood that such a prosthesis is held effectively against the inside surface of the vessel by the presence of the clamps being held elastically in the closed position under drive from the prosthesis. In addition, since the clamps are closed simultaneously with the prosthesis being put into place, it is relatively easy to install such a prosthesis.

Figure 6 shows a variant embodiment of a prosthesis of the invention.

The vascular prosthesis shown in Figure 6 comprises a lattice 100 itself made up of eight elastic metal wires, such as the wires F1, F2, and F3, that are twisted together in a manner that is described in greater detail below. Along the length of the lattice, these wires define a plurality of successive regions, which going downwards in Figure 6 are as follows:

- an end zone 102 having eight loops 104;
- successive middle regions 106, each presenting peripheral rings of twisted nodes 108;
- an end region 111 having end twists 112.

Considering the wire F1:

- the loop 104 is constituted by the wire F1 twisted into a loop over at least half a turn; and

each node 108 is constituted by a twist of the wire F1 together with an adjacent wire such as F2 or F3 over one or more turns.

Thus, on either side of each double-twisted node referenced 115 where the wire is twisted through an even number of half-turns, and in particular through two half-turns, each wire strand forming the node extends in two directions that are parallel to each other and close together.

In contrast, with so-called triple-twisted nodes 117 where the wire is twisted through an odd number of half-turns, in particular three half-turns, each wire leaves in two directions that form between them an angle that is much less than 180°, for example a right angle or even an acute angle as shown, so as to constitute two adjacent sides of one of the meshes of the lattice.

As shown in Figure 6, in the example shown, the wire F1 starts from a twist 112 and then forms successively a node 115, a node 117, a node 115, another node 115, a node 117, a node 115, another node 115, a loop 113, a node 115, another node 115, a node 117, a node 115, another anode 115, a node 117, a node 115, and another twist 112.

In this embodiment, each clamp referenced 116 is formed by a single metal wire 120 whose middle portion is engaged and twisted around wires defining the lattice, and whose two free ends are curved outwards to form hooks 118.

More precisely, the wire 120 is twisted from a node 115 about two angularly offset strands that diverge. Each branch of the wire 120 is then twisted with the following twisted node and thereafter extends transversely along a mesh diameter, the two arms meeting by extending parallel to each other towards respective curved ends.

Thus, as in the preceding embodiment, it is deformation of the mesh carrying the clamp that causes

the clamp to open or close, the two arms with curved ends moving relative to each other.

In the embodiment of Figure 7, the hooks 218 are formed by simple, generally-rectilinear rods, each having one end secured to the end of a mesh and its other end projecting outwards a little from the generally cylindrical outside surface of the lattice.

In this embodiment, when the meshes are open, the pointed ends of two hooks 218 overlap. However, when the two adjacent meshes disposed on either side of the mesh carrying the clamp are closed, then the hooks are spaced apart from each other.

In order to put such a prosthesis into place, it is necessary to have two means for holding meshes closed for each of the clamps. Initially, they are applied to the two adjacent meshes so as to enable the clamp to be held open. After the prosthesis has been properly positioned, the two adjacent meshes are released, thereby leading to the clamp closing and the two hooks penetrating into the wall of the blood vessel.

Translation of the title and the abstract as they were when originally filed by the Applicant. No account has been taken of any changes that may have been made subsequently by the PCT Authorities acting ex officio, e.g. under PCT Rules 37.2, 38.2, and/or 48.3.